

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

)
) MDL No. 1456
) Master File No. 1:01-CV-12257-PBS
) Sub-Category Case No. 1:08-CV-11200
)

THIS DOCUMENT RELATES TO:
*United States ex rel. Linnette Sun and Greg
Hamilton, Relators*
v.
Baxter Healthcare Corporation

) Judge Patti B. Saris
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**DECLARATION OF SHAMIR PATEL IN SUPPORT OF
BAXTER HEALTHCARE CORPORATION'S
MOTION FOR PARTIAL SUMMARY JUDGMENT**

I, Shamir Patel, duly declare under penalty of perjury as follows:

1. I am an attorney at law admitted to practice in the State of New York and the District of Columbia and am an attorney in the law firm of Dickstein Shapiro LLP, counsel for Defendant Baxter Healthcare Corporation. I am familiar with all of the facts and circumstances herein. I make this declaration in support of Baxter Healthcare Corporation's Motion for Summary Judgment in the above-captioned action.

2. Attached hereto as Exhibit A is a true and correct copy of a CMS document titled "Key Milestones in CMS Programs," downloaded from <https://www.cms.gov/History/> (follow "Key Milestones in CMS Programs [WINziped PDF, 2MB]" hyperlink) (last visited Oct. 14, 2011).

3. Attached hereto as Exhibit B is a true and correct excerpted copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, PROTECTING PUBLIC HEALTH AND HUMAN SERVICES PROGRAMS: A 30-YEAR RETROSPECTIVE (2006).

4. Attached hereto as Exhibit C is a true and correct copy of the Department of Health, Education, and Welfare Proposed Rulemaking, *Reimbursement of Drug-Cost—Medical Assistance Program*, Notice of Proposed Rule Making, 39 Fed. Reg. 41480 (Nov. 27, 1974) (codified at 45 C.F.R. Part 250).

5. Attached hereto as Exhibit D is a true and correct copy of HEALTHCARE FINANCING ADMINISTRATION, HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Medicaid-Formula for Determining EAC for Drugs, LIMITATION ON PAYMENT OR REIMBURSEMENT FOR DRUGS – FORMULA FOR DETERMINING ESTIMATED ACQUISITION COST, reprinted in Medicare and Medicaid Guide (CCH) § 28,714 (1977).

6. Attached hereto as Exhibit E is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL, CHANGES TO THE MEDICAID PRESCRIPTION DRUG PROGRAM COULD SAVE MILLIONS, Audit Control No. 06-40216 (Sept. 1984).

7. Attached hereto as Exhibit F is true and correct copy of a DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, Medicare Action Transmittal No. 84-12, MEDICAID – LIMITATION ON PAYMENT FOR DRUGS, reprinted in Medicare and Medicaid Guide (CCH) § 34,157 (1984).

8. Attached hereto as Exhibit G is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OIG MANAGEMENT ADVISORY REPORT – THE USE OF AVERAGE WHOLESALE PRICES IN REIMBURSING PHARMACIES PARTICIPATING IN MEDICAID AND THE MEDICARE CATASTROPHIC COVERAGE ACT PRESCRIPTION DRUG PROGRAM, A-06-89-00037 (Sept. 1989).

9. Attached hereto as Exhibit H is a true and correct copy of OIG Report Concerning Medicaid and Medicare Reimbursement for Drugs, Medicare and Medicaid Guide (CCH) § 38,215 (1990).

10. Attached hereto as Exhibit I is a true and correct copy of Attachment B to Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 1:01-CV-12257 (D. Mass. Feb. 9, 2005).

11. Attached hereto as Exhibit J is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, APPROPRIATENESS OF MEDICARE PRESCRIPTION DRUG ALLOWANCES, OEI-03-95-00420 (May 1996).

12. Attached hereto as Exhibit K is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, EXCESSIVE MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS, OEI-03-97-00290 (Dec. 1997).

13. Attached hereto as Exhibit L is a true and correct copy of the transcript of the President's Weekly Radio Address, 33 Weekly Comp. Pres. Doc. 51 at 2033-34 (Dec. 13, 1997).

14. Attached hereto as Exhibit M is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY – ACTUAL ACQUISITION COST OF BRAND NAME PRESCRIPTION DRUG PRODUCTS, A-06-00-00023 (Aug. 2001).

15. Attached hereto as Exhibit N is a true and correct copy of DEPARTMENT OF HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY – ADDITIONAL ANALYSIS OF THE ACTUAL ACQUISITION COST OF PRESCRIPTION DRUG PRODUCTS, A-06-02-00041 (Sept. 16, 2002).

16. Attached hereto as Exhibit O is a true and correct copy of U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-01-1118, MEDICARE – PAYMENTS FOR COVERED OUTPATIENT DRUGS EXCEED PROVIDERS’ COST (Sept. 2001).

17. Attached hereto as Exhibit P is a true and correct excerpted copy from *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers*, Before the H. Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 107th Cong. (2001) (statement of Rep. James C. Greenwood, Member, H. Subcomm. on Oversight and Investigations).

18. Attached hereto as Exhibit Q is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID PHARMACY – ACTUAL ACQUISITION COST OF GENERIC PRESCRIPTION DRUG PRODUCTS, A-06-01-00053 (Mar. 14, 2002).

19. Attached hereto as Exhibit R is a true and correct excerpted copy from *Reimbursement and Access to Prescription Drugs Under Medicare Part B*, Before the S. Subcomm. on Health Care of the Comm. on Finance, 107th Cong. (2002) (statement of Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services, Washington, DC).

20. Attached hereto as Exhibit S is a true and correct excerpted copy from *Medicare Payments for Currently Covered Prescription Drugs*, Before the H. Subcomm. on Health of the Comm. on Ways and Means, 107th Cong. (2002) (statement of George Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, Department of Health and Human Services, Office of Inspector General).

21. Attached hereto as Exhibit T is a true and correct copy of List of 38 Cases filed against Baxter prior to April 22, 2005.

22. Attached hereto as Exhibit U is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION, AN ADDITIONAL SOURCE OF AVERAGE WHOLESALE PRICE DATA IN PRICING DRUGS AND BIOLOGICALS COVERED BY THE MEDICARE PROGRAM, AB-00-86 (Sept. 8, 2000).

23. Attached hereto as Exhibit V is a true and correct copy of Letter from Congressman Thomas Bliley, Chair of the H. Commerce Comm., to Nancy-Ann Min DeParle, HCFA Administrator (Sept. 25, 2000) (attaching Attachments 6 and 7 to the letter).

24. Attached hereto as Ex. W is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID'S USE OF REVISED AVERAGE WHOLESALE PRICES, OEI-03-01-00010 (Sept. 2001).

25. Attached hereto as Exhibit X is a true and correct copy of U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO-03-184, MEDICARE: PAYMENT FOR BLOOD CLOTTING FACTOR EXCEEDS PROVIDERS' ACQUISITION COST (2003).

26. Attached hereto as Exhibit Y is a true and correct copy of Approval Letter – Advate, from Department of Health and Human Services, Food and Drug Administration to Baxter Healthcare Corporation (July 25, 2003).

27. Attached hereto as Exhibit Z is a true and correct copy of an Advate Fact Sheet, created by Baxter in March 2010.

28. Attached hereto as Exhibit AA is a true and correct copy of Declaration of Larry Guiheen, submitted to this Court on September 30, 2009 in connection with Baxter's Reply Brief in Further Support of its Motion to Dismiss Relators' Complaint, *In re: Pharm. Indus. Average Wholesale Price Litig.*, No. 1:01-CV-12257-PBS (D. Mass. filed Sept. 30, 2009) (Doc. No. 77-7).

29. Attached hereto as Exhibit BB is a true and correct copy of DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES, TRANSMITTAL 109, CHANGE REQUEST 3331, BILLING INSTRUCTIONS FOR ADVATE RAHF-PFM ON MEDICARE CLAIMS (Aug. 27, 2004).

30. Attached hereto as Exhibit CC is a true and correct excerpted copy of *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*; Proposed Rule, 69 Fed. Reg. 47488, 47566 (August 5, 2004).

31. Attached hereto as Exhibit DD is a true and correct copy of the CMS's Blood Clotting Factor Furnishing Fees from 2005 through 2011, downloaded from https://www.cms.gov/McrPartBDrugAvgSalesPrice/20_ClotFactorFurnishFee.asp (last visited Oct. 14, 2011).

32. Attached hereto as Exhibit EE is a true and correct copy of the October 5, 2011 Settlement Agreement and Release between Baxter and Ven-A-Care.

33. Attached hereto as Exhibit FF is a true and correct copy of the CMS List of Blood Clotting Factors, dated 5/2/2011, downloaded from <https://www.cms.gov/Reimbursement/downloads%5Clistofbloodclottingfactors.pdf>.

34. Attached hereto as Exhibit GG is a true and correct excerpted copy from Consent of the United States of America to the Relators' Dismissal with Prejudice of Claims Pursuant to 31 U.S.C § 3730(b)(1).

35. Attached hereto as Exhibit HH is a true and correct copy of the Court's Order of Dismissal with Prejudice of Certain Claims Against Baxter Defendants.

I hereby swear that the foregoing statements are true to the best of my knowledge, information, and belief.

Dated: October 19, 2011

/s/ Shamir Patel

Shamir Patel

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Washington, DC 20006

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Counsel for Defendant Baxter Healthcare
Corporation

CERTIFICATE OF SERVICE

I hereby certify that I, Shamir Patel, an attorney, electronically filed the foregoing DECLARATION OF SHAMIR PATEL IN SUPPORT OF BAXTER HEALTHCARE CORPORATION'S MOTION FOR PARTIAL SUMMARY JUDGMENT with the Clerk of the Court for the District of Massachusetts using the Court's CM/ECF system on October 19, 2011. I also caused a true and correct copy of the foregoing document to be delivered to all counsel of record by electronic service via LexisNexis File & Serve, for posting and notification to all parties.

/s/ Shamir Patel
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